DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 8, 2015

OLYMPUS MEDICAL SYSTEMS CORP.
% Daphney Germain-Kolawole
Regulatory Affairs Project Manager
Olympus Corporation of the Americas
3500 Corporate Parkway, PO Box 610
Center Valley, PA 18034-0610

Re: K150142
Trade/Device Name: Single Use Balloon Dilator V (with Knife)
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS, FGE
Dated: August 27, 2015
Received: August 28, 2015

Dear Daphney Germain-Kolawole,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150142

Device Name
Single Use Balloon Dilator V (with Knife)

Indications for Use *(Describe)*
These instruments have been designed to be used with an Olympus endoscope for papillotomy and for dilating the major papilla to retrieve biliary stones.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
Single Use Balloon Dilator V (with Knife)

October 7, 2015

I. General Information

■ Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
192-8507
Establishment Registration No: 8010047

■ Official Correspondent: Daphney Germain-Kolawole
Regulatory Affairs Project Manager
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-5691
FAX: 484-896-7128
Email: daphney.germain-kolawole@olympus.com

■ Manufacturer: Aomori Olympus Co., Ltd.
248-1 Okkonoki 2-chome Kuroishi-shi,
Aomori, Japan 036-0357
Establishment Registration No.: 9614641

II. Device Identification

Single Use Balloon Dilator V (with Knife)

■ Device Trade Name: Single Use Balloon Dilator V (with Knife)

■ Common Name: Single Use Balloon Dilator (with Knife)

■ Regulation Number: 876.4300
876.5010

■ Regulation Name: Biliary catheter and accessories
Endoscopic electrosurgical unit and accessories

■ Regulatory Class: II

■ Classification Panel: Gastroenterology and urology

■ Product Code: KNS
FGE

III. Predicate Device and Reference Devices Information

Single Use Balloon Dilator V (with Knife)		
Primary Predicate Device		
Model name	Applicant	510(k) No.
Single use balloon dilator MaxPassTM	Olympus Winter & Ibe, GmbH	K050502
Additional Predicate Device1		
Model name	Applicant	510(k) No.
CRE Dilatation Balloon	Boston Scientific Corporation	K112994
Additional Predicate Device2		
Model name	Applicant	510(k) No.
Single Use Preloaded Sphincterotome V	OLYMPUS MEDICAL SYSTEMS CORP.	K122505
Reference Device		
Model name	Applicant	510(k) No.
Autotome RX Sphincterotome	Boston Scientific Corporation	K013153
Single Use Biliary Balloon Dilator	OLYMPUS MEDICAL SYSTEMS CORP.	K143303

IV. Device Description

The subject device consists of the balloon and the papillotomy knife for endoscopic sphincterotomy. The predicate device consists of a closed guidewire lumen, and the subject device consists of a partially open guidewire lumen. The partially open guidewire lumen is called the C-Channel design, and the exchange operation of the guidewire is added.

V. Indications for Use

These instruments have been designed to be used with an Olympus endoscope for papillotomy and for dilating the major papilla to retrieve biliary stones.

VI. Comparison of Technological Characteristics

・Compared to the predicate devices, the subject device has three lumens and one C-channel.

VII. Summary of non-clinical testing

・The following performance testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device works as intended.

- ・Dimensional verification
- ・Endoscope compatibility
- ・Knife operation
- ・Papillotomy resistance
- ・Tensile strength
- ・Balloon deflation time
- ・Balloon burst strength
- ・Balloon fatigue
- ・Package integrity

・Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The following standards have been applied to the Single Use Balloon Dilator V (with Knife).

- ・IEC 60601-1
- ・IEC 60601-1-2
- ・IEC 60601-1-6
- ・IEC 60601-2-2
- ・IEC 60601-2-18
- ・ISO 10993-1
- ・ISO 10993-5
- ・ISO 10993-7
- ・ISO 10993-10
- ・ISO 10993-11
- ・ISO 11135
- ・ISO 14971
- ・ASTM F-1980-07

VIII. Conclusion

When compared to the predicate device, the Single Use Balloon Dilator V (with Knife) do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.